AMENDMENT TO THE CLAIMS

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Original) A method of treating muscle spasms comprising administering an effective anti-spasmodic amount of tizanidine by a route of administration selected from the group consisting of buccal administration and sublingual administration.

2. (Original) The method of claim 1 wherein the tizanidine is administered in a pharmaceutical composition or dosage form that releases 80% or more of the tizanidine in 20 minutes or less.

3. (Original) The method of claim 2 wherein the pharmaceutical composition or dosage form releases 80% or more of the tizanidine in 5 minutes or less.

4. (Currently amended) The method according to claim 1, wherein the effective anti-spasmodic amount of tizanidine increases ~~A method of increasing~~ the bioavailability of tizanidine ~~by administration of an effective anti-spasmodic amount of tizanidine by a route selected from the group consisting of buccal administration and sublingual administration~~.

5. (Original) The method of claim 4 wherein the increase in bioavailability is an increase of 10% or more of the average area under the curve extrapolated to infinity of the plasma concentration of tizanidine over time of a first population patients who are administered tizanidine sublingually or buccally compared to a second population of patients who are administered an equivalent dose of tizanidine by swallowing an immediate release tablet.

6. (Original) The method of claim 5 wherein the first population and the second population are the same and the time that tizanidine is administered by swallowing an immediate release tablet is separated from the time that tizanidine is administered sublingually or buccally by a washout period.

7. (Original) The method of claim 5 wherein the increase in bioavailability is an increase of 20% or more.

8. (Original) The method of claim 5 wherein the immediate release tablet comprises the excipients colloidal silicon dioxide, stearic acid, microcrystalline cellulose and anhydrous lactose.

9. (Original) The method of claim 8 wherein the immediate release tablet is ZANAFLEX™.

10. (Currently amended) ~~A method of reducing~~ The method according to claim 1, wherein the effective anti-spasmodic amount of tizanidine reduces variations in the bioavailability of tizanidine between individuals in a patient population receiving tizanidine therapy ~~by administration of tizanidine by a route selected from the group consisting of buccal administration and sublingual administration~~.

11. (Original) The method of claim 10 wherein the patient population is the patients receiving tizanidine therapy at a single health care facility.

12. (Original) The method of claim 11 wherein the population includes a proportion of the population who have been administered tizanidine orally but do not respond well and are subsequently administered tizanidine sublingually or buccally and wherein the reduction in variation among the population is improvement in the suppression of muscle spasms of the proportion of the population that does not respond well to orally administered tizanidine as evidenced by observations of health care personnel or medical records.

13. (Original) The method of claim 11 wherein the patient population is the patients receiving tizanidine therapy from a single doctor.

14. (Original) The method of claim 13 wherein the population includes a proportion of the population who have been administered tizanidine orally but do not respond well and are subsequently administered tizanidine sublingually or buccally and wherein the reduction in variation among the population is improvement in the suppression of muscle spasms of

the proportion of the population that does not respond well to orally administered tizanidine as evidenced by observations of health care personnel or medical records.

15. (Original) The method of claim 10 wherein the bioavailability is measured by the area under the curve of blood plasma over time extrapolated to infinity (AUC_{inf}) and the reduction in variation in bioavailability is measured using the relative standard deviation of AUC_{inf}.

16. (Original) The method of claim 15 wherein the reduction is about 10% or more.

17. (Original) The method of claim 16 wherein the reduction is about 20% or more.

18. (Original) The method of claim 17 wherein the reduction is about 30% or more.

19. (Original) A tizanidine pharmaceutical composition or oral dosage form especially adapted to release tizanidine in the mouth comprising tizanidine and a pharmaceutically acceptable carrier.

20. (Original) The tizanidine pharmaceutical composition or oral dosage form of claim 19 further comprising an acidulant.

21. (Original) The tizanidine pharmaceutical composition or oral dosage form of claim 20 wherein the acidulant is selected from the group consisting of ascorbic acid, benzoic acid, citric acid, fumaric acid, lactic acid, malic acid, sorbic acid and tartaric acid.

22. (Original) The tizanidine pharmaceutical composition or oral dosage form of claim 21 wherein the acidulant is citric acid.

23. (Original) The tizanidine pharmaceutical composition or oral dosage form of claim 19 wherein 80% of the tizanidine is released in twenty minutes or less after being taken into the mouth.

24. (Original) The tizanidine pharmaceutical composition or oral dosage form of claim 23 wherein 80% of the tizanidine is released in five minutes or less after being taken into the mouth.

25. (Original) The tizanidine pharmaceutical composition or oral dosage form of claim 19 that is a congealing liquid pharmaceutical composition comprising a hydrophilic polymer and a poly-protic hydrogen bonding cross-linking agent.

26. (Original) The tizanidine pharmaceutical composition of claim 25 wherein the cross-linking agent is tannic acid.

27. (Original) The tizanidine pharmaceutical composition of claim 25 wherein the hydrophilic polymer is selected from the group consisting of proteins, polysaccharides, cellulosic polymers and polyacrylates.

28. (Original) The tizanidine pharmaceutical composition of claim 27 wherein the protein is selected from the group consisting of gelatin, hydrolyzed gelatin, albumin and collagen.

29. (Original) The tizanidine pharmaceutical composition of claim 27 wherein the cellulosic polymer is selected from the group consisting of hydroxyethylcellulose, hydroxypropylcellulose and hydroxypropylmethylcellulose.

30. (Original) The tizanidine pharmaceutical composition of claim 27 wherein the polysaccharides is selected from the group consisting of pectin, carrageenan, alginic acid and their salts, guar gum and tragacanth gum.

31. (Original) The tizanidine pharmaceutical composition or oral dosage form of claim 19 that comprises a core tablet containing tizanidine sheathed in an annular body of pharmaceutical excipients.